

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rashida A. Karmali

Serial No. : 10/826,083 Group Art Unit : 1743
Filed : 04/16/2004 Examiner : Jill A. Warden
For : Specimen Collection, processing and analytical Assembly

SECOND DECLARATION OF Rashida A. Karmali Under 37 C.F.R. 1.132

1. I am the inventor in the above referenced application. I am currently Chief Executive Officer Chief Financial Officer and Chief Scientific Officer of SavviPharm Inc, located in New York, New York. I am beneficial owner of this invention. I have a Ph.D in Biochemistry (1976) and have published over 100 scientific articles. I also have a JD and an MBA.
2. The Office Action mailed on July 3, 2007, included the following Statements:

#1. Declarations must be accompanied by evidence.

Response. The inventor had stated in her March 19, 2007 Declaration that one with ordinary skill in the art can clearly understand that a collecting device for 5ml or 10 ml of blood will require a larger tube, larger amounts of chemicals and have higher prices per tube than a smaller collecting device, smaller amounts of chemicals and lower prices per tube were used to collect < 2ml blood. Thus, the cost of collecting and processing smaller amounts of fluids would be lower and this would result in lower cost and commercial success of the product. Exhibit 1, page 85 shows pricing for 15 ml and 50 ml conical tubes. The packing size is 500/pk and it is 109/pk for 15 ml and 119/pk for 50ml tubes. These are available in bulk for each color.

As an example, if 25 patients were to be screened in any one clinic for multiple blood tests, that clinic would need to buy 500pk size supplies for each color. The nurse would then have to prepare a rack of tubes of each size for each patient before she draws the samples.

In the present invention, the nurse would go straight to the pack containing tubes of each color and use that pack per patient. The supply bought will be commensurate with need and purchasing power of the clinic.

This exhibit also demonstrates that when taking larger volumes of blood as is the case now , larger tubes are used.

An important consideration of the present invention limiting the sample to 2000 μ l is that there is no waste of blood and problem of biohazard waste is reduced because of small sample. The test to be carried out is not affected because usually small amounts of blood are used in clinical testing.

#2 The inventor also expects that by packaging different color-coded containers for each patient in one package, will reduce errors, enable faster sample testing and throughput and better and accurate storage of patient samples.

The inventor has talked to different vendors (potential licensees) and concluded that no such product as the present invention, is available on the market. Applicant submits Exhibit 1, page 89, a copy of the Catalog showing different color-coded baskets and test tube racks. When I inquired with different vendors if they carried supplies of different color tubes in multiples of 1 or 2 they did not have them. From the supply chain point of view, an ordinary person skilled in the art would seriously consider purchasing packages of different – color coded containers packed together for the following reasons: 1) it would enable collection, processing and analysis of samples of each patient (per tray or package) and reduce errors due to mix-up of samples, 2) a set of different color-coded containers would cost much less than buying individual containers in bulk as shown in Exhibit 1, 3) it would facilitate mass sample testing and throughput, 4) it would reduce errors in storing patient samples.

I therefore believe that there is need for the invention and it promises to have commercial success and be useful in reducing sample sizes and hazardous waste disposal.



I hereby declare that all statements made hereto to my knowledge are true, and all statements made on information and beliefs are believed to be true; and further, that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon.

By: Rashida A. Karmali

Rashida A. Karmali, Ph.D, JD. MBA

Date: October 3, 2007

50mL Conical Tubes

- Flat-top screw caps with inner seal prevent potential leaks during centrifugation
- Graduated from 2.5-50mL for accurate measurement of contents
- Available in both sterile and non-sterile packaging
- Self-standing tubes keep specimen upright

ITEM	DESCRIPTION	PK	\$
RF5344	50mL Polypropylene Self-Standing Conical Tubes Non-Sterile • 30 x 115mm	500/pk	119
RF5340	50mL Polystyrene Conical Tubes • Non-Sterile • 29 x 118mm	500/pk	159
RF5341	50mL Polypropylene Conical Tubes • Non-Sterile • 29 x 118mm	500/pk	159
RF5343	50mL Polypropylene Conical Tubes • Sterile • 29 x 118mm	500/pk	219
RF5345	50mL Polypropylene Self-Standing Conical Tubes Sterile • 30 x 115mm	500/pk	129
RF5342	50mL Polystyrene Conical Tubes • Sterile • 29 x 118mm	500/pk	219

Tube racks available on pgs 88-90



MATERIAL SPECIFICATIONS

Polypropylene

- Autoclavable
- Virtually unbreakable
- Resistant to acids, solvents, and alkalis at ambient temperatures
- Safely centrifuged up to 5000RPM/3000g

Polystyrene

- Clearly view contents
- Safe to use with mild aqueous solutions and bases or weak acids
- Safely centrifuged up to 3400RPM/1000g
- Non autoclavable

Acrylic

- Ultimate clarity
- Break-resistant
- Safely centrifuged up to 5000RPM
- Non autoclavable

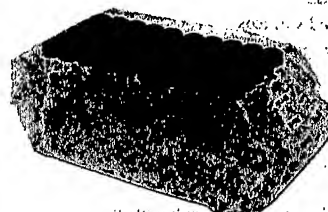
15mL Threaded Conical Tubes and Caps

Prevent Leaks

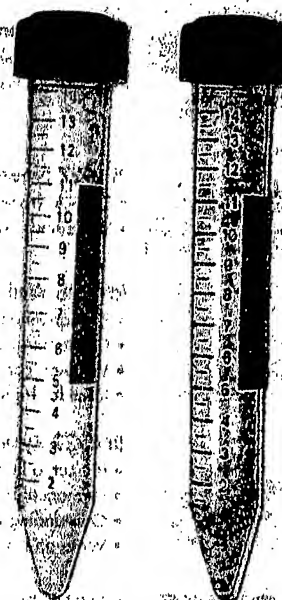
- Clear acrylic tubes have 6000+g spin rate, polypropylene maximum RCF 10,000
- White graduation marks measure from 1.5-14mL and are easy to read
- Writing area eliminates need for labels
- Available in both sterile and non-sterile acrylic or polypropylene

ITEM	DESCRIPTION	PK	\$
RF2437	15mL Conical Centrifuge Tubes with Screw Caps Polypropylene • Non-Sterile • 17 x 120mm	500/pk	109
RF2438	15mL Conical Centrifuge Tubes with Screw Caps Polypropylene • Sterile • 17 x 120mm (50/rack)	500/pk	119
RE2435	15mL Conical Centrifuge Tubes with Screw Caps Acrylic • Non-Sterile • 17 x 120mm	500/pk	199
RF2436	15mL Conical Centrifuge Tubes with Screw Caps Acrylic • Sterile • 17 x 120mm (50/rack)	500/pk	109

Sample Available
Non-sterile only



RF2436 & RF2438
Sterile tubes are
Rnase/Dnase and
Pyrogen-free



RF2437-38
Polypropylene
Virtually unbreakable

RE2435-36
Acrylic
Greater clarity



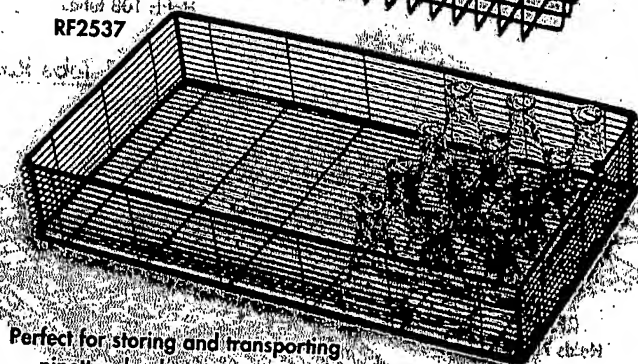
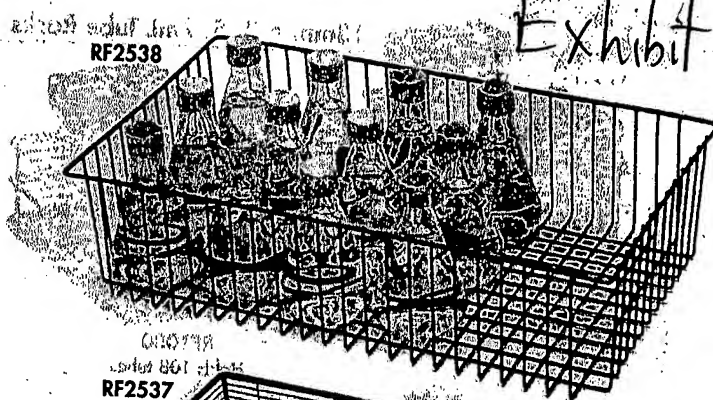
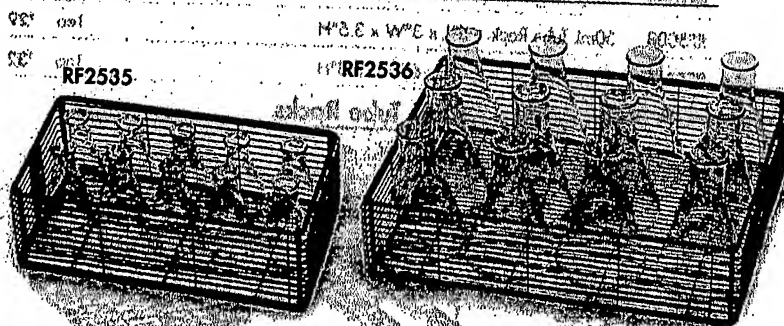
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Durable Baskets Stand Up to Extreme Lab Conditions

- Epoxy-coated steel wire construction resists rust, corrosion, solvents, acids, and alkalis
- Autoclavable for easy cleaning
- Available in four sizes

NEW

ITEM	DESCRIPTION	PK	\$
RF2535	Epoxy Coated Wire Basket • 11"L x 6"W x 3.5"H	1ea	'49
RF2536	Epoxy Coated Wire Basket • 14"L x 11"W x 3.5"H	1ea	'59
RF2537	Epoxy Coated Wire Basket • 20"L x 11"W x 3.5"H	1ea	'69
RF2538	Epoxy Coated Wire Basket • 24.5"L x 14"W x 6"H	1ea	'79



Perfect for storing and transporting pipettes, beakers, measuring devices, and other labware

Designed Specifically for Freezer Use

- Constructed of Delrin® to safely handle extreme cold and hot temperatures (-40°F to 250°F)
- Resistant to acids, solvents, and most harsh laboratory chemicals
- Available in a variety of colors for coding and organization of specimens
- Autoclavable
- Fully assembled

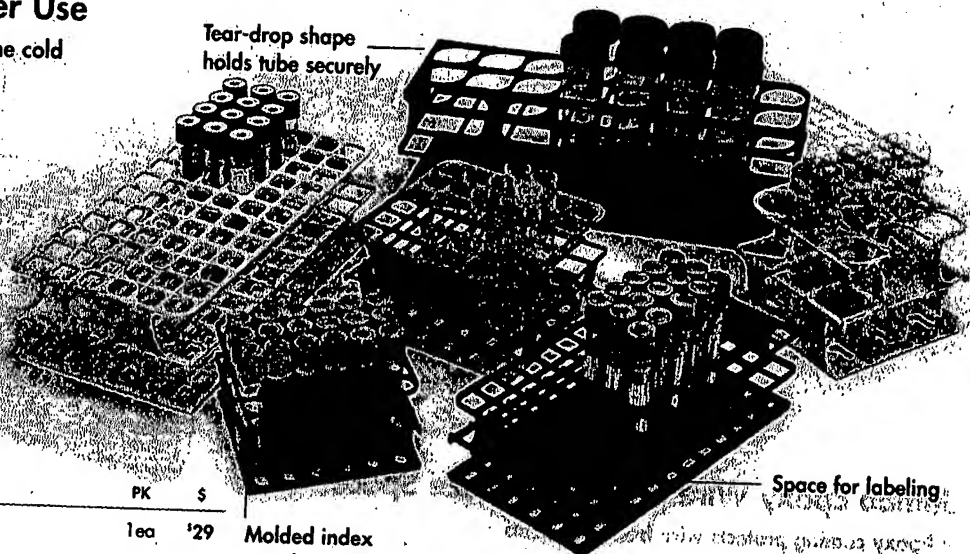
GN	RD	BL	WH
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Green Red Blue White

Specify color when ordering

ITEM	DESCRIPTION	PK	\$
RF5300 + color	13mm 72-Capacity Freezer Full Rack • 8"L x 4.1"W x 2.3"H	1ea	'29
RF5301 + color	16mm 72-Capacity Freezer Full Rack • 9.8"L x 5"W x 2.75"H	1ea	'29
RF5302 + color	30mm 24-Capacity Freezer Full Rack • 4.1"L x 4.3"W x 3.3"H	1ea	'31
RF5303 + color	13mm 36-Capacity Freezer Half Rack • 4.1"L x 4.1"W x 2.3"H	1ea	'19
RF5304 + color	16mm 36-Capacity Freezer Half Rack • 5"L x 5"W x 2.75"H	1ea	'19
RF5305 + color	30mm 9-Capacity Freezer Half Rack • 4.3"L x 4.3"W x 3.3"H	1ea	'19

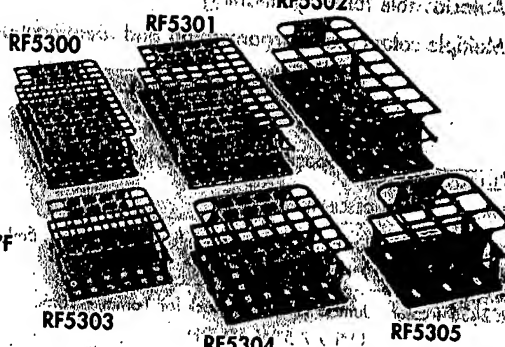
Tear-drop shape holds tube securely



Molded index coordinates help you locate specimens quickly

Space for labeling

Safe to use in extreme conditions: -40°F to 250°F



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